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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,346	11/30/2001	Irwin Klein	830004-2001.2	5520

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/998,346	KLEIN ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *26-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGEMENT OF RESPONSE TO THE RESTRICTION REQUIREMENT AND STATUS OF THE CLAIMS

1. The response to the restriction requirement filed 09/06/07 is acknowledged, entered and considered. Claims 1-40 are now pending in the application.

ELECTION WITHOUT TRAVERSE

2. Applicant's election without traverse of Group I (claims 1-25) in the reply filed on 09/06/07 is acknowledged. Hence, the Office action is directed to the merits of claims 1-25 as *per* elected invention. Applicant is requested to cancel non-elected claims in the next communication.

OBJECTION OF THE SPECIFICATION, DRAWINGS AND CLAIM

3. The specification is objected on page 3, line 23 in the recitation "of-30^{0}C and 70^{0}C, preferably-10^{0}C and 50^{0}C and more preferably 0^{0}C and 30^{0}C" and on page 11, lines 9 and 10 in the recitation "at 4^{0}C" and "at-4^{0}C", respectively. Amendment of the specification to recite "of-30 ^{0}C and 70 ^{0}C, preferably-10 ^{0}C and 50 ^{0}C and more preferably 0 ^{0}C and 30 ^{0}C" and on page 11, lines 9 and 10 in the recitation "at 4 ^{0}C" and "at-4 ^{0}C", respectively would obviate this objection.

The drawing is objected because Figures 6A-6F and 6I have no description in the specification. The only description recited in the specification is for Figures 6G and H.

Also, there is no Figure 7 (A-I), only one figure is disclosed as Figure 7. Appropriate correction is required.

Claim 2 is objected in the recitation "about-30^{0}C to 70^{0}C". Amendment of the claim to recite "about -30 ^{0}C to 70 ^{0}C" is suggested.

OBJECTION TO TRADEMARKS AND THEIR USE

4. The use of the trademarks "Lumelec™", "THUMPER®" and "EDGE SYSTEM™" have been noted in this application. Some of the trademarks have not been capitalized, they should be capitalized wherever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner, which might adversely affect their validity as trademarks.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirements are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

CLAIM REJECTION-35 U.S.C. § 102(b)

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Dietzen (U.S. Patent No. 5,795,789).

The prior art of Dietze ('789 patent) discloses a stabilized liquid solution for use in calibrating assays of thyroid function containing albumin and known amounts of at least two analytes selected from a group consisting of total thyroxine, free thyroxine, total triiodothyronine (T_3) and free triiodothyronine, and optionally thyroid stimulating hormone (See abstract). On col. 5, the '789 patent discloses the preparation of the calibration solution comprising T_3, serum albumin and buffer which may include water to stabilize T_3 formulation at room temperature of 25 ^{0}C, further comprising a pharmaceutically acceptable excpient, and as such meets the limitations of claims 1-3. The '789 patent states that Figure 6 depicts a calibration curve for total T_3 assay using a calibration solution according to this invention, wherein the calibration solution contains only serum albumin as a protein component. The protein serves as an acceptable stabilizing milieu TSH. Preferably, albumin from bovine serum is used as the albumin, although, other sources of albumin are acceptable. Serum albumin is useful in a range between 40 g/L and 80 g/L which mimics the physiologic protein concentration of serum. Thus, the reference shows that other sources of albumin is acceptable with various concentrations, and as such meets the limitations of claims 14-17 (See e.g., col. 3, lines 30-62).

On col. 4 lines 1-3, the '789 patent states that to enhance the buffering capacity of the calibration solution buffers which maintain pH in a range between 6.0 to 8.0 may be required. The pH 6-8 is within the claimed ranges of pHs of claims 22-25. Also, on col. 4, lines 40-46, the '789 patent states that T_3 is preferably used in a range between 0 and 12 µg/L solution since these concentrations span the physiologically relevant range of T_3 concentrations found in human serum. Exemplary solutions are prepared with T_3 content of 0, 1.0, 2.0, 4.0 and 9.0 µg/L. In the presence of 60 g/L bovine serum albumin, and as such meet the ranges claimed in claims 18-21.

The Examiner acknowledges that the prior art does not teach the various half-life of T_3 claimed in claims 9-13. However, the prior art clearly discloses the same formulation of a composition comprising T_3, serum albumin and water in a form of buffer to stabilize the claimed formulation as claimed. The various half-life claimed are drawn to inherent property, which, result from the stabilization process of the claimed formulation, and as such, since the prior art formulation is substantially the same as the claimed one, it must inherently possess the claimed various half-life, and must inherently be true inasmuch as the same and/or substantially the same formulation is used.

The cited reference above does not disclose the intended use of the various suitable mode of administration as claimed in claims 4-8, although, the '789 patent uses standard solution for determination of thyroid function; nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA

1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969). Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed product/composition as taught by the reference anticipates claims 1-25 as drafted.

6. Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kunst et al (U.S. Patent No. 5,342,788).

The prior art of Kunst et al ('788 patent) discloses a standard solution containing thyroxine-binding globulin (TBG) and thyroxine or triiodothyronine dissolved in a buffer solution is used for calibration in a method for the determination of thyroxine (T_4) or triiodothyronine (T_3) in serum, wherein both human and bovine TBG can be used (See abstract). On examples 5 and 7, the '788 patent discloses the preparation of the calibration solution comprising T_3, serum albumin and buffer which may include water to stabilize T_3 formulation at room temperature of 25 ^{0}C, further comprising a

pharmaceutically acceptable excpient, and as such meets the limitations of claims 1-3. The '788 patent states that it is not necessary to add human serum albumin, which is of course suitable, to the standard. Although, human serum albumin can be used, equally suitable are the universally and easily obtainable and much more preferable albumins, for example from bovine or horse serum. Human serum albumin, bovine serum albumin or horse serum albumin and particularly bovine serum albumin, is preferably used as the albumin. The albumin is preferably used in an amount of 40 to 80 mg/ml. It is particularly preferable to use albumin in a physiological amount, i.e., at a range of from 50 to 70 mg/ml. Thus, the reference shows that other sources of albumin is acceptable with various concentrations, and as such meets the limitations of claims 14-17 (See e.g., col. 3, lines 57-68).

On col. 4 lines 1-4, the '788 patent states that to enhance the buffering capacity of the calibration solution buffers which maintain pH in a range between 6.0 to 8.0 are suitable as the buffer system, preferably those with pH value of 6.5 to 7.5. The pH 6-8 is within the claimed ranges of pHs of claims 22-25. Also, on col. 3, lines 46-51, the '788 patent states that if a standard solutions is used to determine T_3, it contains T_3. The T_3 is preferably used in an amount in the ranges of from 0.5 to 12 ng/ml. It is particularly preferable to add T_3 in a physiological amount i.e., in the range of from 0.5 to 8 ng/ml., and as such meet the ranges claimed in claims 18-21.

With respect to the various half-life of T_3 claimed in claims 9-13, the '788 patent on col. 4 states that this solution is also stable over long periods of storage because of its composition, since it is produced from standardized individual substances, it always

has a uniform composition and therefore yields reproducible values. In lyophilized form the formulation is stored for at least eight weeks and in liquid form, the formulation remains stabilized for at least 18 months. Thus, the claimed half-life of claims 9-13 is within the ranges disclosed by the '788 patent.

The cited reference above does not disclose the intended use of the various suitable mode of administration as claimed in claims 4-8, although, the '789 patent uses standard solution for determination of thyroid function; nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969). Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed product/composition as taught by the reference anticipates claims 1-25 as drafted.

CITATION OF RELEVANT PRIOR ART

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Satoh (U.S. Patent No. 5,051,406) discloses a pharmaceutical composition using albumin as a carrier, as well as to a process fro producing the pharmaceutical formulation thereof.

Rubin (U.S. Patent 5,158,978) teaches a method for the treatment of patients with acute cardiovascular comprising by administering a therapeutically effective amount of thyroid hormones.

CONCLUSION AND FUTURE CORRESPONDANCE

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mohamed/A. A. M./
Examiner, Art Unit 1654

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654